

1. DEFINITIONS

Accredited veterinarian	A veterinarian approved by the Administrator of APHIS, USDA, in accordance with Title 9, Code of Federal Regulations, Part 161, to perform functions required by cooperative State-Federal animal disease control and eradication programs.
Administrator	The Administrator of APHIS, USDA, or any other official to whom the Administrator has delegated authority to act in his or her stead.
Animal	Any sheep or goat.
APHIS	The Animal and Plant Health Inspection Service, United States Department of Agriculture.
Area Veterinarian in Charge (AVIC)	The veterinary official of Veterinary Services, APHIS, United States Department of Agriculture, who the Administrator assigned to supervise and perform official animal health work in a State(s).
Breed Associations Registries	Organizations maintaining the animals' permanent records of and ancestry or pedigrees, individual animal identification and ownership of records.
Board	The State Scrapie Certification Board.
Commercial Class	A Voluntary Scrapie Flock Certification Program Class designed for scrapie monitoring.
Commingling	Animals grouped together having free physical contact.
Contemporary Lambing/kidding group	A group of ewes/does and their offspring that are managed as a separate unit from lambing/kidding for at least 60 days, with sufficient records to confirm this separation. If the same lambing/kidding facility is used for multiple contemporary lambing/kidding groups, the facility must be cleaned and disinfected in accordance with Section IV, subpart c, between groups.
Deputy Administrator	The Deputy Administrator for Veterinary Services, APHIS, United States Department of Agriculture, or any other official to whom the Deputy Administrator has delegated authority to act in his or her stead.

Exposed Animal	Any animal which has been in the same flock at the same time within the previous 60 months as a scrapie positive animal, excluding limited contacts.
Exposed Flock	A flock that had contained, within the previous 60 months, an animal which was later confirmed as scrapie positive in another flock. The flock will be Classified as exposed until the diagnostic sampling requirements of Section III have been met.
Flock Status	<p>Classification of a flock with regard to scrapie or the Voluntary Scrapie Flock Certification Program. The possible statuses include:</p> <ul style="list-style-type: none"> •Certifiable C, B, A or Certified •Commercial •Exposed •Infected •Trace •Source •Pending; <p>The Flock's status would remain with the flock when a change of ownership, management or premises occurs. Individual animals will retain the flock of origin's status unless:</p> <ul style="list-style-type: none"> •for enrolled flocks, they were commingled with animals from a lower status flock • animals that originated from infected or source flocks, they are now designated as high, medium, or lower risk in purchasing flocks.
Flock/herd	<p>All animals maintained on any single premises; and all animals under common ownership or supervision on two or more premises with animal interchange between the premises. Two flocks may be maintained on a single premises if they are</p> <ul style="list-style-type: none"> 1-managed separately, 2-have no commingling, and 3-have separate flock records. <p>The term flock will be used in lieu of herd or other terms for groups of animals throughout the remainder of this document.</p>

Flock Plan	<p>A written management agreement designed by the flock owner, an accredited veterinarian and an APHIS Representative or State animal health official. The State Scrapie Certification Board will review flock plans only for enrolled flocks. Each participant agrees to specified actions to control the spread of scrapie from, and eradicate scrapie in, an infected flock, or a source flock.</p>
High-Risk Animal	<p>An animal determined by epidemiologic investigation to face a high risk of developing clinical scrapie, because the animal was:</p> <ul style="list-style-type: none"> •progeny of a scrapie-positive dam ; OR •tested QQ at codon 171 and born in the same contemporary lambing group as: <ul style="list-style-type: none"> a-progeny of a scrapie-positive dam; OR b-a scrapie-positive dam or sire; OR •not tested at the codon 171 site and born in the same contemporary lambing group either as: <ul style="list-style-type: none"> •progeny of a scrapie-positive dam: •scrapie-positive dam or sire.
Infected Flock	<p>Any flock in which an APHIS representative or State animal health official has determined an animal to be scrapie-positive. A flock will not be considered infected after it has completed the flock plan requirements including removal of the high risk animals.</p>
Limited Contact	<p>Contacts between animals off of the flock's premises at fairs, shows, exhibitions and sales, and for rams, at ram tests, and not during or up to 60 days after lambing/kidding. Limited contacts do not include commingling.</p>
Lower-Risk Animal	<p>An animal determined by epidemiological investigation to face a lower risk of developing clinical scrapie than a high or medium-risk animal, because the animal was:</p> <ul style="list-style-type: none"> •Progeny of a scrapie-positive sire; OR •In a flock with only a scrapie-positive sire; OR

- born in a flock prior to the estimated infection date; OR
- In a flock in which a scrapie-positive ewe had not lambed;
OR
- Tested RR at the 171 codon site and born in the same
contemporary lambing group as:
 - 1-progeny of a scrapie-positive dam; OR
 - 2-a scrapie-positive dam or sire.

Medium-Risk
Animal

An animal determined by epidemiological investigation to face a medium risk of developing clinical scrapie because the animal was:

- tested QR at codon 171 site and born in the same
contemporary lambing group as:
 - a-progeny of a scrapie-positive dam; OR
 - b-a scrapie-positive dam or sire.

Concern exists over Codon 171 QR animals not developing clinical scrapie and silently transmitting scrapie exists. Producers writing a flock plan should consider the carrier possibility for Codon 171 QR animals and further reduce risks of transmitting scrapie.

National Scrapie
Oversight Committee

A committee composed of the same interests as were represented on the Scrapie Negotiated Rulemaking Advisory Committee. The committee will:

1. Be appointed by APHIS based on consultation with the organizations on the Scrapie Negotiated Rulemaking Advisory Committee
2. Will meet at least once a year, and
3. give guidance to APHIS on the policies and practices of the Voluntary Scrapie Flock Certification Program.

Nonparticipating Flock

A flock that is not enrolled in the Voluntary Scrapie Flock Certification Program.

Official Identification

A unique individual identification for the following in the Voluntary Scrapie Flock Certification Program:

- All animals one year old and older
- All animals less than one year old when ownership changes except those sold in slaughter channels; which meet the

following criteria:

- permanent
- secure
- unique numbers from a central repository
- producer responsible for traceability

The types of Voluntary Scrapie Flock Certification Program-approved identification are:

- electronic identification
- Flank or Ear tattoo
- tamper-resistant Ear tag

Official Laboratory	A laboratory designated by a State and approved by the Administrator to perform the Program-required scrapie diagnostic procedures. The National Veterinary Services Laboratory, United States Department of Agriculture, Ames, Iowa, is the reference laboratory for diagnostic procedures.
Owner	An individual, partnership, company, corporation, or other legal entity which has legal or rightful title to a flock of animals, regardless if the animals are subject to a mortgage.
Premises	The ground, area, buildings, and equipment communally shared by a flock of animals.
Program	The Voluntary Scrapie Flock Certification Program (VSFCP)
Scrapie	<p>A nonfebrile, transmissible, insidious, degenerative disease affecting the central nervous system of sheep and goats.</p> <p>Scrapie a transmissible spongiform encephalopathy, may cause the following signs in affected animals:</p> <ul style="list-style-type: none">• weight loss despite retention of appetite• behavioral abnormalities• pruritus (itching)• wool pulling• biting at legs or side• lip smacking• motor abnormalities such as incoordination• high stepping gait of forelimbs• bunny hop movement of rear legs• swaying of back end• increased sensitivity to noise and sudden movement• tremor

- “star gazing”
- head pressing
- recumbency

Scrapie-positive Animal	An animal which has had a clinical diagnosis of scrapie confirmed through tests by an official laboratory.
Scrapie Suggestive	<p>An animal which:</p> <ol style="list-style-type: none"> 1. When an official laboratory examined its brain tissue histologically displayed some but not all of the scrapie characteristics; 2. Has not been confirmed as a scrapie-positive by any other test at an official laboratory.
Scrapie Suspect	An animal which displays clinical scrapie suggestive signs.
Source Flock	<p>A flock in which at least one animal, that was diagnosed scrapie-positive at less than 54 months of age, was born. A flock will no longer be considered a source flock after it has completed the flock plan requirements including removal of the high risk animals.</p> <p>A single trace to a flock must meet the following criteria to designate the trace flock as a “SOURCE” FLOCK:</p> <ul style="list-style-type: none"> •Confirm identification with DNA and movement, production, and registry records; <p style="text-align: center;">OR</p> <ul style="list-style-type: none"> •Possessing the original ear-tag applied in birth flock; AND •Tamper-resistant ear-tag, or Electronic Identification Implant, or skin tattoo in ear or flank tissue; AND •Movement, production, and registry records. <p>When not meeting the above criteria, two traces will designate a source flock.</p>
State Animal Health Official	A State or State political subdivision-employee working in animal health activities authorized to perform Voluntary Scrapie Flock Certification Program duties.
Status Date	Date on which the State Scrapie Certification Board gave final approval for status change.

Trace Flock	A flock in which one animal, diagnosed scrapie-positive at less than 54 months of age, was born and did not meet the identification requirements outlined under the “Source Flock” definition.
Veterinary Services Representative	An individual employed by Veterinary Services, APHIS, in animal health activities who the Administrator authorized to perform Voluntary Scrapie Flock Certification Program duties.
Voluntary Scrapie Flock Certification Program	<p>A voluntary State/Federal/Industry Cooperative effort established and maintained to:</p> <ol style="list-style-type: none"> 1. reduce scrapie’s occurrence and spread; and 2. identify flocks which have been free of scrapie signs and exposure over specified time periods.

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II. ADMINISTRATIVE PROCEDURES

The Voluntary Scrapie Flock Certification Program is a voluntary cooperative program with the following participants:

- Animal Producers;
- Allied Industry;
- APHIS;
- State Animal Health Officials’;
- Accredited Veterinarians; and
- Animal Breed Registries and Associations.

A. Oversight of the Voluntary Scrapie Flock Certification Program

The National Scrapie Oversight Committee reviews the Voluntary Scrapie Flock Certification Program and makes individual recommendations to the Deputy administrator regarding:

- methods to detect, control, and eradicate scrapie; and
- policy and technical improvements in the Voluntary Scrapie Flock Certification Program.

The Committee will:

- meet at least once a year;
- consult with scientific and technical experts;
- consider program improvement suggestions in developing a scrapie control effort;
- develop an ultimate eradication effort that is effective and producer- friendly;
- discuss issues;
- make individual recommendations; and
- provide enrolled and nonenrolled producer input to the program and educational materials on scrapie and the control program.

B. State Scrapie Certification Board

A State Scrapie Certification Board will be formed within each State to:

- Administer the Voluntary Scrapie Flock Certification Program;
- Review Program enrollment and status advancement applications;
- Review situations which may result in a reduction of certification status or dismissal from the program;
- Review Flock Plans for enrolled infected or source flocks; and
- Educate producers regarding scrapie and scrapie control.

The State Scrapie Certification Board will be comprised of

- APHIS' Area Veterinarian-in-charge,
- Animal Producer(s),
- Allied Industry Representatives,
- An Accredited Veterinarian, and
- State animal health official in cooperating States.

State Certification Boards should:

- be composed of an odd number of members;
- be chaired by an enrolled producer;
- encourage Board members to be enrolled in the program; and
- support the program at State and Local sheep events and in the sheep-producing community; and
- meet at least annually and more as needed.

The Area Veterinarian-in-charge, in cooperation with the State animal health official, flock owners and allied industry organizations, will appoint members to the State Scrapie Certification Board. Boards may delegate their authority to subcommittees and may enact more stringent requirements to fit their State's scrapie situation.

C. Application for Program Status

The State Scrapie Certification board will review enrollment and advancement applications within 60 days of the application receipt. The enrollment or advancement date is when the State Board approves the application. Flock owners will submit applications with an official flock identification list and supporting documentation by an accredited veterinarian having knowledge of the flock.

State or Federal Animal Health Officials will provide each enrolling Program participant and their accredited veterinarian, with an educational scrapie review. This will enable the enrolling participant to declare to the State Scrapie Certification Board that he or she believes the flock is:

- Free of scrapie or
- affected with scrapie

If, at enrollment, a flock is either suspected or confirmed infected, a flock plan must be written as outlined in section IV subpart c.

D. Duties of Program Participants

Under the Voluntary Scrapie Flock Certification Program, APHIS will maintain a records database for use in certification and epidemiological investigations.

APHIS, in cooperation with State animal health agencies and accredited veterinarians, will:

- Conduct epidemiological investigations;
- Perform inspections; and
- Provide guidance and education.

Flock owners will:

- Establish and maintain records;
- Identify animals with official identification as specified by the program standards;
- Report scrapie suspect animals to a State animal health official, APHIS representative, or an accredited veterinarian; and
- Ensure that tissue samples are collected and submitted for diagnostic purposes in accordance with Section IV subpart a.

Breed registries and associations, livestock markets and packers will;

- Maintain liaison with flock owners;
- Assist in providing flock owners with information on the Voluntary Scrapie Flock Certification Program;
- Facilitate the information exchange regarding transfer of animals; and
- Encourage information reporting between flock owners, State animal health agencies, and APHIS.

E. Entering Premises

Participating flock owners must allow State Scrapie Certification Board representatives to enter premises to carry out Program procedures. While on a premises, such personnel must use sound procedures to minimize the risk of transmitting diseases.

F. Providing Services to Livestock Owners

Flock owners are responsible for handling their animals during delivery of program services. The Deputy administrator may contract with:

1. Accredited Veterinarians,
2. Paraprofessionals,
3. Other State and Federal agencies,
4. Management of privately owned firms,

needed to assist APHIS representatives and State animal health official in collecting tissue samples, identifying animals, and in performing other program activities.

G. Advancement of Certification Status

A flock may advance in certification status if it has met the following:

1. Not have had Scrapie diagnosed in the flock;
2. Not been deemed a source flock for the time period as required by the applicable certification status;
3. Have filed a completed advancement application; and
4. Fulfilled the current certification's status requirements.

H. Downgrading of Certification Status

When an enrolled flock is designated as infected or source following a thorough examination and epidemiological investigation, the flock's certification status will change to infected or source. The flock will develop and complete a flock plan in accordance with Section IV subpart c. The status will then be reinstated as Certifiable Class C or other applicable status.

Certification statuses of enrolled flocks having acquired animals from lower status enrolled or nonenrolled flocks will drop to the lowest acquisition level. If the enrolled flock obtained animals from a nonenrolled flock, the enrolled flock's status will downgrade to Certifiable Class C.

An enrolled flock's certification status may be in jeopardy if:

- Its animals have been allegedly commingled with lower certification status or nonenrolled animals and then returned to their original flock; or
- Its animals were subjected to embryo transfer from a lower certification status flock.

The State Scrapie Certification Board may revoke a participating flock's status and remove it from the Program if its owner or manager has not complied with the standards. The flock may reenter the Program after fulfilling Board-determined requirements. The Board may also refer suspected cases of:

- Fraud,
- Misrepresentation, or
- Violation of State or Federal Laws

to the appropriate authorities.

I. Appeal

The State Board will notify the flock owner whose certification status is being reduced or removed from the Program. The State Board will give an opportunity to the affected flock owner to present his or her views to the Board. The flock owner may appeal to the Administrator within 30 days of the Board's decision.

III. PROGRAM CLASSES AND REQUIREMENTS

GENERAL PROVISIONS FOR ALL CLASSES

The Voluntary Scrapie Flock Certification Program intends to:

- Monitor enrolled flocks; and
- Identify flocks considered to be scrapie-free.

Scrapie-free status means not having had clinical disease or exposure over time.

Any sheep or goat owner or manager may enroll and participate in the Voluntary Scrapie Flock Certification Program by certifying to the State Scrapie Certification Board their intent to comply with applicable Program provisions.

Except for the Commercial Class, the enrolled flock owner or manager will agree to:

1. Immediately report animals with:

- Scrapie-suggestive signs, and
- Otherwise, undiagnosed disease

to a State or Federal animal health official or an accredited veterinarian. These animals will not be sold for breeding or slaughter purposes.

2. Ensure that tissues are collected from animals with:

- Signs suggestive of scrapie, and
- Otherwise, undiagnosed disease

and submitted to an official laboratory in accordance with Section IV subpart a. Other tissues will be submitted in accordance with the applicable class requirements or at the State Scrapie Certification Board's request.

3. Officially identify:

- all animals one year old or over, and
- all animals less than one year old when ownership changes except those sold in slaughter channels.

Official identification for the above stated animals meets the following criteria:

- permanent,
- secure,
- unique, and
- producer responsible for traceability.

The types of Program approved identification are:

- electronic identification,
- flank or ear tattoo, and
- tamper-resistant ear tag.

4. Maintain records as stated in the specific Program class. Producers must keep records at least five years after an animal dies or leaves the flock.

5. Allow:

- Breed associations and registries,
- Livestock markets, or
- Packers

to disclose records to State or Federal animal health officials in tracing source flocks or exposed animals.

6. Notify Board about acquisitions from:

- Nonparticipating flocks, or
- Lower status enrolled flocks

during flock inspections.

7. Make the following available for inspection:

- Animals and
- Records

by State or Federal Animal Health Officials and State Scrapie Certification Board representatives, given reasonable prior notice.

8. Have the necessary facilities and personnel available to assist in inspecting each animal's identification when needed.

CERTIFIABLE CLASSES C, B, A, AND CERTIFIED

Certifiable Classes C, B, A, and Certified require many of the same actions with some differences. The Certifiable Classes require the same actions in the areas of:

- Identification,
- Diagnostic Submissions,
- Evidence of scrapie,
- Ram acquisitions,
- Use of semen,
- Commingling with lower status or nonenrolled animals,
- Animals from foreign countries,
- Transfer of certification status with purchased animals, and
- Enrollment Time Limits.

The Certifiable Classes C, B, A, and Certified require different actions in these areas:

- Entry Eligibility,
- Animal Records, and
- Inspections.

The Commercial Class requirements are addressed elsewhere in this section.

The following specifies the same actions for each of the respective Certifiable Classes:

IDENTIFICATION

Participants must officially identify:

- All animals one year old or older; and
- All animals less than one year old when sold, except those in slaughter channels.

DIAGNOSTIC SUBMISSIONS

Any animal in the flock with:

- Scrapie-suggestive signs and
- Otherwise, undiagnosed disease

must be necropsied and brain, spleen, and mesenteric lymph nodes submitted as per Section IV, subpart a. Such animals will not be sold for breeding or slaughter.

EVIDENCE OF SCRAPIE

Enrolled flocks identified as infected or source will be handled according to Section IV, subparts b and c. The flock's status will change to infected or source when so identified and will be removed when it has completed a flock plan. Flock's remaining in the program will be reinstated to at least Day One, Certifiable Class C.

RAM ACQUISITIONS AND MOVEMENTS

Enrolled flocks owning and using rams CONSISTENTLY with the SAME nonenrolled flocks, would not lose status and would be eligible to advance if they meet the following conditions:

- Ram was not born in or transited a Source, Trace, Infected or Exposed Flock;
- In nonenrolled flock, ram was with ewes ONLY at breeding and not at or near lambing;
- In nonenrolled flock, ram was isolated from ewes in nonbreeding season or returned to enrolled flock; and
- Satisfied the other requirements to advance to the next Class or remain at Certified.

COMMINGLING

An enrolled flock's certification status will be in jeopardy if animals are:

- Commingled with animals from a nonparticipating flock, other than limited contacts, and then returned to the original flock. Rams not meeting the conditions outlined in the Ram Acquisitions and Movements section and ewes would be commingled if freely exposed to nonenrolled or lower status animals; or
- Recipients of embryos from a nonparticipating or lower status flock.

The State Scrapie Certification Board will determine the certification status when needed.

USE OF SEMEN AND EMBRYOS

Enrolled flocks may use semen from lower or nonenrolled flocks with no status drop or advancement delay. The semen may not originate from:

- Infected Flocks,
- Source Flocks,
- Trace Flocks, or
- Exposed Flocks.

Enrolled flocks may receive embryos with no status drop or advancement delay if the embryos originated from:

- Enrolled flocks with the same or higher status;
- Foreign country free of scrapie; or
- Flock in foreign country that has met program standards equivalent to current class.

Recipient ewes must meet the flock's Certification Class requirements.

The donor animal's flock status is that of the embryos transfer date. For example, if the collection date status was C, and the transfer date, B, the donor's flock status is B. Enrolled flocks may not use germplasm from any donor found to be scrapie-positive.

IMPORTED ANIMALS

If a foreign country:

- Has an equivalent certification program; or
- is recognized free of scrapie by APHIS' standards,

imported animals from such countries may enter the program at the appropriate level if they are not at any time commingled with animals of a lesser status.

CERTIFICATION STATUS TRANSFER WITH PURCHASED ANIMALS

A purchasing flock may retain the certification status of acquired enrolled animals if they:

- Do not commingle enrolled and nonenrolled animals; and
- Do not commingle higher status with lower status animals.

When establishing a new flock entirely from an enrolled flock, the flock of origin's status will transfer to the new flock if:

the new flock notifies the State Board and submits an enrollment application within 30 days of the animal's arrival on the farm.

ENROLLMENT TIME LIMITS

1. Premises on which scrapie has never been diagnosed may enroll with no down time.
2. Premises on which scrapie has been diagnosed;
 - High, medium and lower risk animals identified;
 - Flock completely depopulated;
 - Premises thoroughly cleaned and disinfected;

Flock plan completed; and
Premises had no sheep for one year;
such may enroll after one year's down time.

3. Flocks in which scrapie has been diagnosed;
No high or medium risk animals produced;
Flock plan completed; and
Premises thoroughly cleaned and disinfected;
such may enroll immediately after the flock completes the flock plan.

4. Flocks in which scrapie has been diagnosed,
Only high risk animals depopulated;
Premises thoroughly cleaned and disinfected; and
Flock plan completed in a minimum of two years;
such may enroll after the flock completes the flock plan.

The following specifies different actions for the respective Certifiable Classes.

ENTRY ELIGIBILITY

All Certifiable Class C flocks which:

- Have not had scrapie diagnosed in the last year; and
- Have not been designated a source flock in the last year

are eligible for entry into the Certifiable B Class. The flock's owner or manager and an accredited veterinarian will certify that, to the best of their knowledge, the flock has not had evidence of scrapie within the last year.

Class B and A flocks must meet the same type of requirements to advance to the next class except the length of time is different. A Class B flock advancing to Class A must

- Not have had scrapie diagnosed;
- Not been designated a source flock; and
- Not have had evidence of scrapie in the last THREE years.

Class A flocks advancing to Certified must meet the same requirements for Five years.
Certified Flocks may remain Certified as long as they meet all the Certified requirements.

ANIMAL RECORDS

Class C participants must keep the following information for each animal:

1. Official and any secondary identification number,
2. Sex,
3. Breed,
4. Date of Birth,
5. The flock of origin and date of entry, and
6. Disposition--date and cause of death, if known, or movement date and to whom.

Classes B, A, and Certified are required to keep Class C information plus:

- 1-Sire and Dam's Official and any secondary identification numbers; and
- 2-Progeny's Official and any secondary identification numbers and sex.

INSPECTIONS

State and Federal Animal Health Official representatives must inspect Classes C and Certified flocks every 11-13 months and B and A every 5-7 months, respectively. Inspectors will check:

- Each animal for official identification and scrapie signs; and
- Records for:
 1. Completeness,
 2. Accuracy, and
 3. All acquisitions, departures, births, and deaths.

COMMERCIAL CLASS

The Commercial Class, open to any flock, is mainly for slaughter lamb producers who wish to monitor for scrapie but cannot justify the time and expense the Certifiable Classes require. The Commercial Class's goal is:

- To increase industry's involvement in scrapie control by:
 - Providing practical scrapie monitoring that may be implemented by producers with no need to progress through the "Certifiable" classes.

IDENTIFICATION

Participants must officially identify all male animals one year old or older.

ANIMAL RECORDS

Participants must keep the following records:

1. All one year and older male animals' official and secondary identification number,
2. Breed,
3. Acquisition date and flock of origin, and
4. Disposition--date and cause of death if known, or date of movement and to whom.

INSPECTIONS

Authorized State or Federal Animal Health Officials must inspect participating flocks every 11-13 months. Inspectors will check:

- Each male animal one year old or older for official identification;
- The flock for signs of scrapie; and
- The records for completeness and accuracy.

ROUTINE MONITORING FOR EVIDENCE OF SCRAPIE

Commercial Class flocks will be monitored for evidence of scrapie by ONE of the following methods:

- One animal per 1000 ewes or less must be submitted for examination each year. This animal should be a cull more than two years old or routine death loss.
- If any black face rams or ewes more than two years old are in the flock, at least one of any animals that die during the year must be submitted.

- When any animal 4 years old or older is necropsied by an accredited veterinarian, tissues will be submitted for scrapie diagnosis.
- The brain examination requirement would be waived if a flock had no death/cull losses in animals more than two years old during the reporting period.

SLAUGHTER INSPECTION

An accredited veterinarian will inspect ALL cull ewes in enrolled Commercial Class flocks for clinical signs suggestive of scrapie:

- Prior to slaughter and
- While they are still identifiable to the flock of origin.

EVIDENCE OF SCRAPIE

Any animal(s) showing clinical scrapie signs (e.g., neurologic signs) in a Commercial Class flock are not to be used for breeding purposes. Upon death, these animals must be necropsied and tissues (brain, spleen, and mesenteric lymph nodes) submitted in accordance with Section IV subpart a.

- Enrolled flocks identified as infected or source, will be handled according to Section IV, subparts b and c.
- The flock's status will change to infected or source which will be removed when it has completed the flock plan.
- A Commercial Class participating flock designated as infected or source is not eligible to reenter the Commercial Class.

ACQUISITIONS AND MOVEMENTS

Commercial Flock participants:

- Must not purchase animals from infected or source flocks;
- Are encouraged to purchase animals from Certifiable Classes C, B, A, or Certified; and
- Must officially identify all male animals when ownership changes, except for those moving in slaughter channels.

COMMERCIAL CLASS STATUS MAINTENANCE

A Commercial Class participant will maintain its class indefinitely or until it enters the Certifiable Classes, provided the flock continues to meet the Commercial requirements.

IV. SCRAPIE INFECTED/SOURCE/EXPOSED/TRACE FLOCKS

Subpart a-Laboratory Procedures and Test Interpretation

A. GENERAL CONSIDERATIONS

Official laboratories will examine all Voluntary Scrapie Flock Certification Program tissues. The official laboratory will report diagnostic findings to:

- The submitter,
- The State Scrapie Certification Board
- APHIS

B. LABORATORIES

A cooperative system of States and National Veterinary Services Laboratories will assist official laboratories in ensuring quality control.

C. DIAGNOSTIC TESTS

Official laboratories must use currently recognized procedures for:

- Examining tissues, and
- Establishing a presumptive scrapie diagnosis.

Official laboratories shall use histopathological examination such as described by:

- L. D. Miller, et al.(1) and
- Race, R., et al. (2)

as the primary diagnostic criteria. Official Laboratories shall submit appropriate specimens to the reference laboratory, the National Veterinary Services Laboratories, U.S. Department of Agriculture, Ames, Iowa, to confirm the presumptive diagnosis.

The reference laboratory routinely:

- Examines brain tissue histopathologically and
- Conducts immunohistochemical surveys for prion protein (PrP SC) (3)

for a final and official diagnosis. Western blot techniques or other subsequently evolving methodologies acceptable to the veterinary community may augment histopathology and immunohistochemistry in diagnosing scrapie.

(1) Miller, L.D., W. Landgraf, and W. D. Taylor. Scrapie: Procedures for laboratory diagnosis. American Association of Veterinary Laboratory Diagnosticians. 28th Annual Proceedings pp.417-420 (1985).

(2) Race, R., B. A. Ernst, A. L. Jenny, W. D. Taylor, et al., Diagnostic Implications of Detection of Proteinase k-resistant Protein in Spleen, Lymph Nodes, and Brain of Sheep. Am J Vet Res 53:883-889 (1992).

(3) Miller, J. M., A. L. Jenny, W. D. Taylor, et al., Detection of prion protein in formalin-fixed brain by hydrated autoclaving immunohistochemistry for the diagnosis of scrapie in sheep. J Vet Diag Invest 6:366-368 (1994).

D. SPECIMEN SUBMISSION

Tissues for diagnostic examination must be submitted to an official laboratory through:

- An accredited veterinarian; or
- State Animal Health Official; or
- APHIS Representative.

Collect tissues immediately after the animal dies and state on the submission form the time between the animal's death and brain's immersion in formalin. If this interval is unknown, please state this on the submission form. Appendix I details brain removal procedures.

- Collect the brain with a portion of attached anterior spinal cord.
- Divide the brain and anterior spinal cord in half longitudinally. Start the cut rostrally between the cerebral hemispheres and proceed caudally.
- If possible, perfuse one half of the brain with fixative after flushing the vascular bed with saline or water.
- Place the fixed half of the brain in at least one liter of 10 percent neutral buffered formalin solution. The optimum fixative penetration is achieved with 20-40 times the tissue volume of fixative. Changes of fixative are desirable.
- Since the fixed tissue will be used for histopathology, keep this tissue separate from the dry ice, other ice packs, or frozen tissues.
- Place the other half of the brain in a separate sealed bag with owner and tissue identification. Keep this half refrigerated with ice packs during transit to an official laboratory.

- Collect the spleen and several mesenteric lymph nodes and place in separate bags with owner and tissue identification. Keep these tissues refrigerated with ice packs during transit to an official laboratory.

Properly prepare all tissues for transit:

- Place the separately bagged tissues in another bag with owner and tissue identification to facilitate shipment.
- Collect and include the official identification with the submission.
- Properly prepare and separate the formalin fixed tissue with the refrigerated tissue for shipment. Do not allow the formalin fixed tissues to freeze. Place the owner's name and animal identification on the container.
- Deliver refrigerated fresh tissue to a laboratory within 36 hours of collection. Otherwise, freeze this tissue for shipment.

Subpart b-EPIDEMIOLOGY

A. GENERAL CONSIDERATIONS

Subpart b applies to ALL:

- Infected flocks
- Source flocks
- Trace flocks
- Exposed flocks

B. TRACEBACK OF SCRAPIE-POSITIVES

A Veterinary Services or State Scrapie Certification Board designated epidemiologist will:

- Thoroughly investigate each scrapie-positive animal
- Submit an investigation report to:
 1. The State Scrapie Certification Board
 2. APHIS
 3. Any appropriate State animal health agencies.
- Identify all:
 1. Source flocks
 2. Trace flocks
 3. Exposed flocks

as soon as possible.

C. EPIDEMIOLOGIC INVESTIGATION

1. The investigation will identify:

- Exposure risk to the flock and individual animals by naming the critical dates pertinent to the estimated introduction of infection. These dates include:
 1. Birth date of the infected animal(s)
 2. Date the infected animal(s) entered the flock
 3. Date the infected animal(s) lambed or kidded.

- Source flocks
- Trace flocks
- Exposed flocks
- “High Risk” individual animals
- “Medium Risk” individual animals
- “Lower Risk” individual animals.

2. An APHIS or State Scrapie Certification Board representative will:

- Notify, in writing, owners of animals and flocks identified by the above investigation within 30 days of naming the flocks and animals as required by Title 9 CFR Part 79.3;
- Inform owners about scrapie; and
- Explain the risks associated with scrapie.

Subpart c-FLOCK PLAN

A. GENERAL CONSIDERATIONS

The flock plan's goals are to:

- Eliminate scrapie from the flock, and
- Prevent the spread of scrapie to other flocks.

The flock plan is intended to be used by:

- Infected flocks
- Source flocks
- Trace flocks or
- Exposed flocks.

The following will cooperatively develop flock plans:

- Flock owner or manager
- An accredited veterinarian
- APHIS
- State Animal Health Official.

The State Scrapie Certification Board will review plans only for enrolled flocks.

B. RECLASSIFYING CERTIFICATION STATUS

When an enrolled flock is designated as infected or source following a thorough examination and epidemiological investigation, the flock's certification status will be changed to either infected or source. Other flocks affected by the reclassification will be notified in writing:

- Within 30 days of being identified.

When the infected or source flock has completed the flock plan, the status will be reinstated as Certifiable Class C or other applicable status.

Owners of trace or exposed flocks with high risk animals will be required to submit tissues from all animals 18 months old and older that die in accordance with Section IV subpart a. Such flocks will retain their certification status provided:

- They continue to submit at this rate for up to three years from the notification date; and
- No evidence of scrapie exists in the flock.

C. FLOCK PLAN RECOMMENDATIONS

Flock Plans may include and are not limited to:

- Depopulate high-risk animals;
- Reduce risks associated with new or continuous infection spread to lower risk animals; and
- Clean and disinfect facility and environment, if feasible.
 1. Remove all organic matter from the lambing/kidding and other facilities.
 2. Disinfect with:
 - (a) 2-percent sodium hydroxide (lye) or
 - (b) 0.5-percent hypochlorite (household bleach at a 1:10 dilution)
 - (c) Other effective inactivating agent.
 3. Owners or managers whose flocks have had scrapie may want to use a different lambing/kidding facility.
- Review with the owner/manager the scrapie clinical signs and effective flock monitoring procedures.
- Review the owner/manager's role and procedure for record keeping and animal identification.
- General or specific time frames for completing tasks.
- Placement, if authorized, of a State Quarantine on:
 1. An individual animal or
 2. A group of animals or
 3. An entire flock.

Flocks which have, or previously have had, high-risk animals must meet Certifiable Class C:

- Identification
- Animal Record
- Flock Inspection
- Notification on movement and scrapie suspect animals
- Necropsies and tissue submission, and
- Access to breed association or registry record requirements.

Flock plans may include other scientifically sound practices designed to eliminate scrapie from the flock and to prevent its spread to other flocks.

Subpart d-QUARANTINE AND RELEASE

A. GENERAL PROVISIONS

The State animal health official may exercise quarantine authority consistent with State law and may quarantine and release flocks or individual animals as follows:

1. Restricted animals or flocks

- All animals in an infected flock may be held under State quarantine until the owner/manager has completed the flock plan.
- High-risk, medium risk, or lower risk animals may be individually quarantined until the owner/manger has completed the flock plan.

2. Quarantine Release

- The State animal health official may release the quarantine when the owner/manager has completed the flock plan.

V. FLOCK INFORMATION

The Centers for Epidemiology and Animal Health (CEAH) maintain a national information data base about:

- Enrolled flocks in the Voluntary Scrapie Flock Certification Program
- Infected flocks
- Source flocks.

Interested parties may access this information 24 hours daily, 365 days per year, through dialing 1-800-545-USDA (8732) on a touch tone phone. Select option 4 to connect with the Voluntary Scrapie Flock Certification Phone Query System. Producers may obtain more detailed information on the Phone Query System from an APHIS representative.

The National Animal Health Programs Staff prepares periodic reports from the national data base on enrolled, infected and source flocks. These reports or lists are publicly available through:

- The Phone Query System
- The State animal health representative
- The APHIS representative
- The National Animal Health Program Staff at (301) 734-4363.

The National Scrapie Oversight Committee will use these reports in providing recommendations on the Voluntary Scrapie flock Certification Program.

APPENDIX I

When scrapie is suspected in a live animal, before the necropsy, please contact the previous owner and a State or Federal Animal Health Official. During necropsy, please locate and save all man-made identification devices for use in traces to the original breeder.

Brain Removal

Remove and ship the brain with as little:

- CONTAMINATION
- DISTORTION
- LACERATION

as possible.

The following should enable the prosector to submit a proper specimen:

1. Wear rubber gloves.
2. Cut through the atlanto-occipital joint to separate the head from the carcass.
3. Incise the skin on the midline over the poll, forehead, and nose. Reflect skin laterally to expose the skull, orbits, and caudal part of the nose.
4. Using a postmortem saw, transversely cut 1-2 cm deep across the caudal part of each orbit.
5. Cut on each side of the skull from the foramen magnum to a point 2-3 cm medial to the orbital rim, transecting the transorbital cut. Angle each cut inward at about 45 degrees from the vertical axis.
6. Insert a heavy knife or bone chisel into the transverse cut and slowly pry the skull cap up and back. Take care to prevent the attached meninges from compressing or tearing the brain parenchyma. Cut the meninges as the skull cap is removed. Scissors are more suitable than a knife for cutting these membranous attachments.
7. Cut the meninges between the cerebral hemispheres and over the cerebellum. Reflect the meninges laterally to remove them.

8. Hold the head with the nose or jaw pointing upward to allow gravity to assist in removing the brain from the cranial cavity. Cut through the brain attachments starting with the:

- Olfactory tracts
- Optic nerves and
- Pituitary stalk

and work caudally through the other cranial nerve roots. Gently tease the brain out of the cranial cavity while cutting through the attachments. Allow the brain to drop gently onto a clean, dry surface.

APPENDIX II

SCRAPIE DISINFECTION GUIDELINES

While effective and efficient scrapie disinfectants are needed, little information and few compounds are available. Since the infective agent has not been identified, studies to determine susceptibility to inactivating compounds are costly and complicated.

Until more specific information becomes available, GOOD SANITARY PRACTICES WILL HAVE TO SUFFICE.

The following are based on GOOD SANITARY PRACTICES:

Pastures

- Effective inactivation of the agent will likely destroy the forage.
- Sunlight exposure and pasture rotation are the only practical inactivation alternatives.
- Ploughing the soil should assist in inactivating the agent.

Drylot

- When practical, removing the top 1-2 inches of soil/manure should reduce contamination.
- Bury, till under, or compost the removed material in areas not accessed by animals.

Non-earth Surfaces (cement, wood, metal)

- Remove as much organic material as possible by sweeping, scraping, or other means.
- Wash with a pressure washer using hot water and detergent.
- Apply a solution of 1 part bleach to 10 parts water or 1 can, 13.5 ounces, of lye to 5 gallons of water for a 2 percent lye solution.
- Whenever possible, allow exposure to sunlight.

APPENDIX III

EXHIBITION AND TRANSPORTATION GUIDELINES

Incomplete knowledge on scrapie transmission causes participants concern. Sheep exhibitions and transportation pose a risk for scrapie transmission. The following guidelines may lower these risks:

- Separate according to status, enrolled from nonenrolled sheep by:

1. A vacant pen; or
2. Barn Alley; or
3. Solid physical barrier

sufficient to prevent any physical contact between enrolled and nonenrolled sheep.

- Limited contacts in the show or sales ring:

1. Pose minimal risk of scrapie transmission.
2. Are contacts between animals that occur off the flock's premises and not during or immediately after lambing.
3. Do not include commingling which is where animals are grouped together with free physical contact.

- Lambing increases the exposure potential. Prevent contact with lambing ewes at exhibits or sales.

APPENDIX IV

IDENTIFICATION GUIDELINES

Official identification for certain animals in the Voluntary Scrapie Flock Certification Program meets the following criteria:

- Permanent
- Secure
- Unique
- Producer responsible for traceability

Program approved means of identification are:

- Electronic Identification
- Flank or Ear Tattoos
- Tamper-resistant Ear Tag

Electronic identification users should heed the following:

- Place implants above or dorsal to the auricular or ear cartilage
- Follow the manufacture's directions to properly place electronic implants
- When selling electronically identified animals, except to slaughter, provide an identification certificate stating:

1. Animal's date of birth, sex, breed, registration name and number
2. Electronic Identification number and any secondary identification
3. Breeder's name and address

- Keep the certificate with the animal's records to document receiving electronic identification.

Ear or flank tattoo users should heed the following:

- use two separate tattoos:
 1. A four-character alphanumeric premises code consisting of the State's two letter Postal abbreviation and digits 01-99. Letters may be used if needed.
 2. A four-digit unique individual animal number.

- Apply the premises code and individual animal number in each ear or on the right flank in the wool-free area.
- Animals uniquely tattooed require only an ear or flank tattoo premises code
- Participants are responsible for applying tattoos.

Tamper-resistant ear-tag users should obtain ear-tags that:

- Have been permanently imprinted with the flock's premises code and individual animal number.
- Are tamper-resistant and unique to the Voluntary Scrapie Flock Certification Program.

APPENDIX V

GENETICS AND SCRAPIE

Research results indicate that an animal's genetic makeup

1. influences the length of the incubation period before clinical signs develop and
2. may well influence the strains of scrapie to which an animal is susceptible.

However, inadequate and sometimes contradictory data preclude inclusion of genetic testing as a part of the VSFCP at this time. As more animals are tested and evaluated, the VSFCP will review the evidence and adapt changes as warranted.

In the meanwhile, producers are encouraged to test their animals so more data can be accumulated. Such producers should use the information cautiously in long term breeding programs.

The situation at the time of preparing this documents is as follows:

Suffolk sheep that are homozygous arginine (designated RR in a system where R = the amino acid arginine and Q = the amino acid glutamine) at codon 171 appear to have a lower risk of developing clinical signs of scrapie.

Unanswered concerns include:

- Do 171-QR and/or 171-RR animals still harbor and/or shed the infectious agent, thus representing a hidden risk to their offspring or other animals?
- How does one explain the reports of scrapie in 171-QR and 171-RR animals?
- What is the relationship between the different scrapie strains and the various genetic traits at codons 171, 154 and 136 ?

Current research programs are addressing those issues but the required experiments are both expensive and time consuming, so it may be several years before definitive answers are available. For the meanwhile, producers are encouraged to continue with current risk reduction recommendations.